



STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

M. JODI RELL
GOVERNOR

CRISTINE A. VOGEL
COMMISSIONER

December 8, 2006

Mario P. Infanti
Imaging Sciences International, Inc.
Regulatory Affairs Coordinator
1910 North Penn Road
Hatfield, PA 10440

RE: Certificate of Need Determination Report Number 06-30814-DTR
Imaging Sciences International, Inc.
Use of i-CAT Cone Beam 3-D Dental Imaging System

Dear Mr. Infanti:

On August 8, 2006, with additional information received on October 30, 2006, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") Determination request concerning the use of the i-CAT Cone Beam 3-D Dental Imaging System by the dental community in Connecticut, at an associated capital expenditure of \$155,000 per system. OHCA has reviewed the information contained in your request and makes the following findings:

1. Imaging Sciences International, Inc. proposes to sell its i-CAT Cone Beam 3-D Dental ("i-CAT") Imaging System to private dental clinics in the state of Connecticut.
2. The i-CAT will be used as a replacement for existing Digital Dental Panoramic machines.
3. The i-CAT consists of both the machine itself and a desktop computer which operates the machine. The machine consists of an x-ray source and an amorphous silicon flat panel. Once the acquisition of the scan has been completed, the software in the desktop computer begins the reconstruction of the acquired image data. The resulting computed tomogram allows the axial, coronal, and sagittal view of the patient's head to be displayed on the computer screen. (Source: *iCAT Operator's Manual, Imaging Sciences International, Inc. August 1, 2006*)
4. The i-CAT is primarily used for imaging for dental implants or for orthodontic treatment. As these procedures are considered cosmetic they must be paid for directly by the patients and are not generally covered under medical insurance.
5. The i-CAT costs from \$155,000 to \$175,000 per machine.

An Equal Opportunity Employer
410 Capitol Ave., MS#13HCA, P.O. Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Toll-Free: 1-800-797-9688
Fax: (860) 418-7053

6. On July 3, 2006, Imaging Sciences International, Inc. received authorization from the Food and Drug Administration of the Federal Department of Health and Human Services to market the i-CAT.
7. Code of Federal Regulations, Title 21, Section 1020.30 (b) defines “computed tomography” as the production of a tomogram by the acquisition and computer processing of x-ray transmission data.
8. Section 19a-638 of the Connecticut General Statutes (“C.G.S.”) requires CON approval, regardless of cost, for anyone acquiring, purchasing or accepting donation of a CT scanner, PET scanner, PET/CT scanner, MRI, cineangiography equipment, a linear accelerator or other similar equipment utilizing new technology that is being introduced to the state.

Based on the above findings, OHCA has determined that Imaging Science International, Inc.’s i-CAT Cone Beam 3-D Dental Imaging System is a scanner similar to the other scanners and equipment requiring CON approval. Therefore, providers in Connecticut who wish to obtain and operate the i-CAT Cone Beam 3-D Dental Imaging System must receive CON authorization from OHCA.

If you have any questions concerning this letter, please contact Susan Cole England, Director, Certification, Financial Analysis, and Forecasting at (860) 418-7001.

Sincerely,

Signed by Cristine A. Vogel
Commissioner

c: Rose McLellan, Licensing Examination Assistant, DHSR, DPH

CAV:SCE:lkg